REMARKS

Amendments to the Specification

Applicants herein amend the first paragraph of the specification to update the priority information, now that the parent application has issued as United States patent No. 6,670,455 B1. That paragraph is also re-phrased slightly to improve its grammar. Applicants also insert reference to the enclosed Sequence Listing and provide complete versions of two abbreviated terms, as the Office requested.

Those changes do not incorporate new matter, and Applicants respectfully request the entry of those amendments.

Sequence Listing

At the Office's request, Applicants provide a sequence listing for the four peptide sequences disclosed at page 1 of the specification, and request the Office to use the computer-readable version of that sequence listing previously submitted in Application No. 09/632,627. Applicants also provide a statement to support the filing of that sequence listing. Hence, Applicants submit that the application is in compliance with 37 C.F.R. §§ 1.821-1.825, and respectfully request the Office to associate it with the application.

Information Disclosure Statement

Applicants thank the Examiner for considering the Information Disclosure Statement of November 6, 2003.

Amendments to the Claims

Claims 18-62 are now pending, and claims 1-17 have been cancelled without prejudice or disclaimer. Applicants reserve the right to re-present those claims in future prosecution.

Independent claims 18, 33, and 48 correspond to cancelled claim 9 and recite a composition comprising either a pure form of the protease activating blood clotting factor VII, a pure form of a proenzyme for that protease, or a mixture of the protease and its proenzyme. Those claims merely break apart subject matter that was present in the previously pending claim 9, on which the present Office Action is based. Claims 18, 33, and 48 also recite one or more additional substances. Those additional substances are optional in claims 33 and 48. The independent claims are supported by the application as a whole, including, among other locations, original claims 1-8, and the text at pages 5-6 and original claim 3, where those additional substances are recited in detail. Claims 18, 33, and 48, also incorporate the sequences recited at page 1 of the application and in the attached sequence listing. Therefore, the new independent claims do not raise new issues for searching and examination.

Each independent claim is followed by parallel sets of dependent claims. Claims 19-31, 34-46, and 49-61 recite additional substances that may be present in greater detail. Those additional substances are also supported by the application as a whole, including at pages 5-6 and original claim 3. Claims 32, 47, and 62 recite that the claimed compositions act as biological test reagents. Those claims are supported, for instance, in original claim 8 and cancelled claim 16.

Hence, in summary, the new claims do not introduce new matter and Applicants respectfully request their entry.

Restriction Requirement

Previously pending claims 9-17 had been subject to a restriction requirement. (See the Office Action at pages 2-3.) Applicants elected to prosecute Group I and the Office holds Groups II-IV currently withdrawn. The claims of Group I recited "pharmaceutical compositions" comprising the pure form of the protease activating blood clotting factor VII, its proenzyme, or a mixture of the protease and proenzyme. The new claims recite simply a "composition" comprising "the pure form of the protease activating blood clotting factor VII, the pure form of a proenzyme for the protease or a mixture of both the pure form of the protease and the pure form of the proenzyme." Hence, all of claims 18-62 fall within Group I for examination purposes.

Applicants also respectfully submit that the last full paragraph at page 2 of the Office Action takes Applicants' prior remarks out of context and mischaracterizes part of Applicants' reasons for traversing the restriction requirement. (Reply filed July 25, 2005.) Applicants stated in the reply that the Office's restriction of this application to one of "a pure form of the protease activating blood clotting factor VII" and "a pure form of a proenzyme for the protease" and "a mixture of both the pure form of the protease and the pure form of the proenzyme" is inconsistent with the prosecution of co-pending application 10/701,671, and with the prosecution in parent patent 6,670,455 B1, in which those limitations were examined together. In contrast, Applicants recognize that the "protease inhibitor" had been a subject of a previous restriction requirement in 10/701,671. But Applicants do note that the Office has previously proceeded to

examine the full scope of that limitation and has previously issued claims reciting the entire limitation. (*See* 6,670,455 B1, claims 10 and 12, for example.)

Objection to the Title

The Office objects to the title, stating that "it is too long." (Office Action at page 3.) However, the Office does not cite any statutory or regulatory basis for this objection. Moreover, according to 37 C.F.R. § 1.77 and M.P.E.P. 806.01(a), subsection 6.02(a), the only length restriction on the title of an application is that it be "less than 500 characters." This title is only 169 characters, even when all spaces are included, which is far short of that maximum limit. Hence, Applicants do not amend the title herein and request the withdrawal of this objection.

Objection to the Specification and Request for a Sequence Listing

The Office next requests the amendment of the priority claim in the first paragraph to include the number of the issued parent patent. (*Id.*) Applicants thank the Office for noting the need to update the priority information, have made that correction, and request the withdrawal of this objection.

Third, as discussed above, the Office requests that a sequence listing be associated with this application, and that the paragraph at page 1 introducing the four peptide sequences be amended to provide reference to the sequence listing. (*Id.*) The sequence listing submitted on July 31, 2003, in Application No. 09/632,627 (now U.S. Patent No. 6,677,440) contains the same set of sequences recited in this application. Therefore, Applicants request the Office to use the computer-readable sequence listing from that prior application in this application. Applicants have also included a paper copy of that sequence listing, in compliance with 37 C.F.R. §§ 1.821-1.825, and the

statement to support the filing of the listing, and have amended the specification as the Office requests. It is understood that the Office will make the appropriate changes to the application number, filing date, and other headings of the sequence listing. Accordingly, Applicants request the withdrawal of this objection.

Fourth, the Office requests that SDS-PAGE and PVDF by spelled-out in full in the application. (*Id.*) While Applicants do not believe that this is necessary for one of ordinary skill in the art to understand this invention, Applicants have amended the application accordingly and request that this objection be withdrawn.

Finally, the Office requests that Applicants replace "SDS-PAGE/Western blotting" at page 10, line 13, with just "Western blotting." (*Id.*) Applicants have not made that amendment, because Applicants submit that such an amendment would mis-characterize the application text. The Office appears to believe that "SDS-PAGE/Western blotting" is a single method of detection and that the words SDS-PAGE would therefore be redundant. However, one of ordinary skill in the art reviewing this application in the context of the prior art would understand that the term "SDS-PAGE/Western blotting" means two alternative and complementary methods of detection and not the same method. For instance, a protein may be visualized directly on the gel with a general protein stain such as Coomassie blue; or it can be identified in a Western blot using a stained antibody; or both staining processes can be used. That interpretation is further reinforced by the discussion of SDS-PAGE direct band detection and Western blot detection as two complementary methods of detection of the protein as discussed in the first paragraph on page 2 of the application (re-written above in the

amendment sections). The working example on page 10 is an illustration of those methods. For the reasons above, Applicants request the withdrawal of this objection.

Rejection of Claims 9 and 16 under 35 U.S.C. § 112, Second Paragraph, is Now Moot

The Office rejects the now canceled claims 9 and 16, contending that the recitation of "the protease activating blood clotting factor VII" is indefinite because, in the Office's opinion, it reads on proteins not disclosed in the application. (Office Action at page 4.) The Office suggests incorporating peptide sequence information disclosed at page 1 of the application into the claim, in order to obviate the rejection.

New claims 18, 33, and 48 recite those peptide sequences, according to the Office's suggestion. Hence, Applicants request the withdrawal of this rejection.

Claims 18-62 are Novel according to 35 U.S.C. § 102

1. Rejection over Choi-Miura et al.

First, the Office rejects claims 9 and 16 as allegedly anticipated by Choi-Miura et al. (*J. Biochem.* 119: 1157-1165 (1996); "Choi-Miura"). (Office Action at page 5.) Applicants respectfully traverse that rejection.

In order to establish inherent anticipation, the Office "must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112, emphasis in original. The Office fails to establish a prima facie case of inherent anticipation here because there is no basis to support the Office's contention that the function and characteristics of the claimed compositions necessarily flow from the disclosure of Choi-Miura.

Choi-Miura simply describes the extraction from human plasma aliquots of a protein that its authors call PHBP, and the preliminary sequence characterization of that protein. The paper does not provide details about the protein's function. Nor does Choi-Miura describe the subject matter of any of claims 18, 33, or 48, which require a pure form of the Applicants' claimed protease, a pure form of its proenzyme, or a mixture of that proenzyme and protease. In contrast, Choi-Miura does not describe any particular form of PHBP.

Choi-Miura also does not describe any compositions comprising any of the claimed additional ingredients. Nor does Choi-Miura suggest that any such compositions could act as biological test reagents as claimed in claims 32, 47, and 62.

Finally, the functional properties recited in the claim cannot be ignored when considering anticipation. Choi-Miura was not able to assign any activity or function to its protein. Hence, Choi-Miura does not teach any particular utility or activities of PHBP.

For those reasons, Applicants request the withdrawal of this rejection.

2. Rejection over Niwa et al.

Second, the Office rejects claims 9 and 16, asserting that they are anticipated by Niwa et al. (U.S. Pat. No. 5,648,250). (Office Action at pages 6-7.) Applicants traverse that rejection and submit that it is also rendered moot by new claims 18, 33, and 48.

Niwa et al. relates to tissue-type plasminogen activator (t-PA) protein. That is a different protein than the one which Applicants claim herein and does not share any of the partial sequences recited in claims 18, 33, and 48.

Hence, Applicants request the withdrawal of this rejection.

3. Rejection over Tsujioka et al.

The Office also rejects claims 9 and 16 over Tsujioka et al. under 35 U.S.C. § 102(b). (*Am. J. Hematol.* 61: 34-39 (1999); Office Action at pages 7-8.) Applicants also traverse that rejection and submit that it is also rendered moot by new claims 18, 33, and 48.

Like Niwa et al., Tsujioka et al. relates to tissue-type plasminogen activator (t-PA) protein, which is a different protein than the one claimed in anyone of claims 18, 33 and 48, and does not share any of the partial sequences recited in those claims.

Applicants accordingly request the withdrawal of this rejection.

Provisional Double Patenting Rejections

Finally, the Office rejects claims 9 and 16 under the doctrine of obviousness-type double patenting over pending claims 13 and 16 of Application No. 10/254,662 and claims 30 and 31 of pending application 11/118,396. Applicants acknowledge those rejections, and will consider filing a terminal disclaimer, as appropriate, and at the appropriate time.

In view of the foregoing amendments and remarks, Applicants request the withdrawal of all of the objections and rejections, and submit that this application is in condition for allowance. Hence, Applicants respectfully request the allowance of all of the subject matter of claims 18-62 and the re-joiner of any non elected limitations within those claims.

Please grant any extensions of time required to enter this response and charge any required fees not found herewith to our deposit account 06-0916.

Respectfully submitted,

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Dated: January 24, 2006

By: _____
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Attachments Include:

1. **Amendment Transmittal**
2. **Request for Two-Month Extension of Time**
3. **Sequence Listing in Paper Format**
4. **Request to Use Computer-Readable Sequence Listing of Another Application**
5. **Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§ 1.821-1.825**
6. **Check for $1700.00 for Extra Claims and Extension of Time Fees**